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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS-2012-0019]

RIN 0583-AD49

Eligibility of the Republic of Korea to Export Poultry
Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal poultry products inspection regulations to add the Republic of Korea (Korea) to the list of countries eligible to export poultry products to the United States. FSIS has reviewed Korea's poultry laws, regulations, and inspection system, as implemented, and has determined that they are equivalent to the Poultry Products Inspection Act (PPIA), the regulations implementing this statute, and the U.S. food safety system for poultry.

Under this final rule, slaughtered poultry or parts or other products thereof processed in certified Korean establishments will be eligible for export to the United States. All such products will be subject to re-inspection at United States ports of entry by FSIS inspectors.

EFFECTIVE DATE: [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Dr. Andreas Keller, Director, International Equivalence Staff, Office of Policy and Program Development; Telephone: (202)720-0082.

SUPPLEMENTARY INFORMATION:

Background

On November 27, 2012, FSIS proposed to add the Republic of Korea (Korea) to the list of countries eligible to export poultry products to the United States (77 FR 70724). This final rule is consistent with the provisions of the proposed rule.

As explained in the proposal, section 17 of the PPIA (21 U.S.C. 466) prohibits importation into the United States of slaughtered poultry, or parts or products thereof, of any kind unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient that renders them unhealthful, unwholesome, unfit for human food, or otherwise adulterated. Under the PPIA and the regulations that implement it, poultry products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States. Section 381.196 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by

which foreign countries may become eligible to export poultry and poultry products to the United States.

Section 381.196(a) requires that the standards of a foreign country's poultry inspection system, its legal authority for the inspection system, and the regulations implementing the system be equivalent to those of the United States. These requirements include: (1) ante-mortem and post-mortem inspection performed or supervised by a veterinarian; (2) national government controls over establishment construction, facilities, and equipment; (3) verification of slaughtering of poultry and processing of poultry products by inspectors to ensure that product is not adulterated or misbranded; (4) separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product at certified establishments; (7) controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements under the PPIA and its implementing regulations (9 CFR 381.196(a)(2)(ii)).

The country's inspection program must also impose requirements equivalent to those of the United States with respect to: (1) organizational structure and staffing in

certified establishments to ensure uniform enforcement of laws and regulations; (2) national government control and supervision over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements (9 CFR 381.196(a)(2)(i)).

Inclusion of the country in 9 CFR 381.196 generally implies that the country has a regulatory system equivalent to that of the United States for slaughter and further processing of poultry for all nine processing categories referred to in 9 CFR 417.2 (Slaughter; raw product -- ground; raw product -- not ground; thermally processed -- commercially sterile; not heat treated -- shelf stable; heat treated -- shelf stable; fully cooked -- not shelf stable; heat-treated but not fully cooked -- not shelf stable; and product with secondary inhibitors -- not shelf stable). However, FSIS recognizes that, at the time of the initial equivalence request, a country may not expect to manufacture and export products to the United States that meet the requirements of each of these processing categories. Even so, FSIS determines whether the foreign country has equivalent government oversight, statutory authority and food

safety regulations, sanitation performance standards, hazard analysis and critical control point systems, chemical residue control and microbiological testing programs, and the infrastructure in place to ensure that, if products in any of the nine processing categories were to be exported, the products would meet United States standards of safety and wholesomeness.¹

Evaluation of the Korean Poultry Inspection System

In 2005, the government of Korea requested approval for the importation of Korean poultry products into the United States. Korea stated that its immediate intention was to export two types of ginseng chicken stew products to the United States. FSIS then began to evaluate Korea's inspection system to determine whether it is equivalent to the United States system.

FSIS conducted a document review to evaluate the laws, regulations, and other documentation used by Korea to execute its poultry inspection program. FSIS examined the information

¹ At this time, FSIS is taking steps to publish on its Web site a chart that identifies which of the nine processing categories FSIS specifically reviewed in FSIS in-country audits, and which the Public Health Inspection System (PHIS) is set up to allow to be imported into the U.S. This PHIS-based chart will also reflect any processing category limitations as a result of animal health restrictions for that foreign country, as provided for in 9 CFR part 94. Because FSIS public health policies may change subsequent to the time at which the foreign country is listed in 9 CFR 327.2 or 381.196, or a foreign country may decide to later certify product exported to the U.S. from a processing category not listed for that country on the PHIS-based chart, FSIS will determine whether an in-country audit is necessary before FSIS modifies the PHIS-based chart. Regarding a foreign country's initial request for equivalence for egg products in accordance with 9 CFR 590.910, all the requirements in part 590 must be met as there are no similar processing categories as provided for livestock and poultry products.

submitted by Korea to verify that the following critical points relating to equivalence were addressed satisfactorily with respect to standards, activities, resources, and enforcement:

(1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) HACCP Systems; (5) Chemical Residue Testing Programs; and (6) Microbiological Testing Programs. The document review was satisfactory to FSIS, and FSIS scheduled an on-site review to evaluate all aspects of Korea's inspection program.

In 2008, FSIS conducted an on-site audit of Korea's poultry inspection system and identified systemic deficiencies within five equivalence components. In response to this audit, Korea submitted a corrective action plan that addressed FSIS's findings.

In 2010, FSIS conducted a comprehensive on-site audit to determine whether Korea had satisfactorily implemented all the laws, regulations, and other issuances that FSIS found to be equivalent during the document analysis, and whether the findings of the previous audit had been addressed. The 2010 audit revealed that Korea had fully implemented the corrective action plan that it had submitted in response to the 2008 audit. Nonetheless, the new audit identified new systemic deficiencies in three equivalence components: Statutory Authority and Food

Safety Regulations, Chemical Residue Testing Programs, and Microbiological Testing Programs. During the audit, establishments made changes to address some deficiencies.

In addition to the actions taken during the audit, Korea submitted a corrective action plan on how it would incorporate the actions it took during the audit into its food safety system. FSIS reviewed this corrective action plan and, for the reasons explained below, concluded that Korea had satisfactorily addressed the findings of 2010 audit.

Consequently, on November 27, 2012, FSIS published a proposed rule to find that Korea's poultry inspection system (slaughter and processing) is equivalent to the United States' poultry inspection system and proposing to add the Republic of Korea (Korea) to the list of countries eligible to export poultry products to the United States. For more detailed information on FSIS's evaluation of the Korean poultry inspection system, see the proposed rule (77 FR 70724) and for the full audit report go to

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

Final Rule

After considering the comments received on the proposed rule and discussed below, FSIS concludes that Korea's poultry inspection system is equivalent to the United States' inspection system for poultry and poultry products. Therefore, FSIS is amending its poultry products inspection regulations to add Korea to the list of countries eligible to export poultry products to the United States (9 CFR 381.196(b)). Under FSIS's import regulations, the government of Korea must certify to FSIS that those establishments that wish to export poultry products to the United States are operating under requirements equivalent to those of the United States (9 CFR 381.196(a)).

Although a foreign country may be listed in FSIS regulations as eligible to export poultry to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. These requirements include restrictions under 9 CFR part 94 of the Animal and Plant Health Inspection Service (APHIS) regulations, which also regulate the importation of poultry products from foreign countries into the United States.

Under this final rule, all slaughtered poultry, or parts and products thereof, exported to the United States from Korea will be subject to re-inspection at the United States ports of entry

for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count.

In addition, FSIS will conduct other types of reinspection activities, such as incubation of canned products to ensure product safety and taking product samples for laboratory analysis to detect any drug or chemical residues or pathogens that may render the product unsafe or any species or product composition violations that would render the product economically adulterated. Products that pass re-inspection will be stamped with the official mark of inspection and allowed to enter United States commerce. If they do not meet United States requirements, they will be refused entry and within 45 days will have to be returned to the country of origin, destroyed, or converted to animal food (subject to approval of FDA), depending on the violation. The import re-inspection activities can be found on the FSIS Web site at

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures/fsis-import-reinspection/ct_index9.

Summary of Comments and Responses

FSIS received four comments in response to the proposed rule. One individual and a consumer advocacy organization

opposed the rule, and one individual and three trade associations, representing the poultry and egg products industries, submitted a single comment that supported the proposed rule.

Following is a discussion of the relevant issues raised in the comments and FSIS's responses.

Comment: One individual stated that all poultry from Korea should be banned in the United States. The individual was concerned about the safety of food from foreign countries, including Korea, and animal welfare and inhumane slaughter in Korea. The individual argued that the United States should not import any food from any country.

Response: Under the PPIA, if a country maintains a poultry safety inspection system that is equivalent to that of the United States, it is entitled to ship poultry products to the United States should it seek to do so.

FSIS has conducted a thorough review of Korea's laws, regulations, written procedures, policies, and other official documents, including evaluating whether poultry slaughter establishments maintained good commercial practices consistent with those required in United States poultry slaughter establishments (see 9 CFR 381.65(a)-(b)). These practices ensure that poultry is humanely slaughtered. In addition, FSIS

conducted two on-site verification audits of Korea's poultry inspection system. Taking the findings of the two audits together, FSIS has determined that Korea's poultry inspection system is equivalent to the United States inspection system for poultry and poultry products. The comment has not presented any basis on which FSIS could make a contrary determination.

As stated above, for Korea to be eligible to export poultry to the United States, it must implement and maintain a poultry inspection system that is equivalent to the United States' system. To determine whether Korea maintains an equivalent inspection system, FSIS uses a three-part approach that includes (1) on-going document reviews, (2) periodic on-site system audits, and (3) ports of entry re-inspections. If Korea fails to maintain a poultry inspection system that is equivalent to the United States' system, FSIS will act to suspend or terminate its eligibility to export to this country.

Comment: A consumer advocacy organization stated that, although Korea will initially export only two types of chicken stew, the proposed rule understated the magnitude of future exports to the United States because Korea is being added to the list of countries eligible to export poultry products to the United States with no restrictions.

Response: FSIS has no basis for finding that it understated the magnitude of future exports from Korea to the United States. As described in more detail in the Economic Analysis below, Korea will initially export only two types of chicken stew products to the United States. Because of the limited market in the United States for these products, the projected export volume of these products from Korea is likely to be very small, and thus the impact on the United States economy is likely to be very small as well.

However, it is true that Korea would not be precluded from exporting other poultry products to the U.S. in the future if those products meet all applicable APHIS and FSIS requirements for the products, and Korea certifies that the producing establishments comply with Korean requirements that FSIS has found to be equivalent to applicable FSIS requirements (9 CFR 381.196(a)). Therefore, FSIS agrees that the long-term economic impact of this rule could be more significant than the immediate impact. FSIS does not have any data, however, that it could use to project the long term impact.

Comment: The consumer advocacy organization also argued that Korea should not be added to the list of countries eligible to export poultry products because FSIS's 2010 audit found deficiencies in Korea's inspection system, and FSIS did not

conduct another onsite audit to verify that Korea implemented corrective actions in response to the 2010 audit.

Response: During the 2010 on-site audit of Korea's poultry inspection system, FSIS auditors found that Korea had implemented the corrective actions that it had proffered in response to the 2008 on-site audit findings. In addition, Korea provided records demonstrating that these corrective action plans had been implemented in a manner consistent with FSIS' inspection requirements. This finding provides a basis for confidence that Korea will implement all corrective actions it promises in an acceptable manner.

As the commenter indicated, the auditors found two new problems with the Korean system. The first problem identified by the auditors was in the Statutory Authority and Food Safety Regulations component: Korea's central competent authority (CCA), the Ministry for Food, Agriculture, Forestry and Fisheries, was not requiring establishments to maintain conditions that would allow the government inspectors to inspect adequately each carcass. Specifically, FSIS found that: (a) one of the three establishments audited did not have conveniently located controls (e.g., start-stop switches) that would permit government inspection program personnel to stop the line to conduct a protracted post-mortem inspection of carcasses when

necessary or to prevent adulterated product from entering the chill tank; (b) during the on-site review of records, the Korean inspection regulations did not require inspection stations to have online hand-rinsing facilities with a continuous flow of water within easy access for inspection personnel and establishment personnel to prevent incidental cross-contamination of carcasses resulting from post-mortem inspection procedures, and one establishment audited did not have such online hand-rinsing facilities; and (c) the three establishments audited had 52 footcandles (540 Lux) of lighting at post-mortem inspection stations, in compliance with Korea's inspection regulation, while the United States requires at least 200 foot-candles (2,152 Lux) of shadow-free lighting, with a minimum color-rendering index value of 85, for a system configuration similar to Korea's inspection system and line speed (Streamlined Inspection System (SIS)).

When FSIS discussed these findings with Korea's CCA during the on-site audit, Korea's government inspectors at the establishments instructed the establishments to make the changes necessary to conform to United States requirements for the conditions under which government inspection personnel are to perform their inspections. The establishments proposed immediate corrective actions, and Korean government inspectors

accepted establishments' proposals. In the establishment that did not have conveniently located controls, it implemented immediate corrective action by relocating the controls (e.g., start-stop switches) to a convenient location. All the three establishments adjusted lighting at post-mortem inspection stations to 200 foot-candles of shadow-free lighting with a minimum color index value of 85. In addition, Korea immediately revised its export requirements for the U.S. to require export facilities to have inspection stations with online hand-rinsing facilities. This document was provided to the auditor before the conclusion of the audit. Korea subsequently provided records, including a photograph, showing that the audited establishment without on-line hand-rinsing facilities had installed such facilities.

FSIS auditors verified the immediate corrective actions while still in Korea. However, the auditors told Korea that it needed to submit a comprehensive corrective action plan that included a systematic solution to prevent recurrence of these deficiencies.

Following the audit, in July of 2011, Korea provided supporting documentation demonstrating that it had issued new requirements for: (1) inspection stations to have conveniently located controls (e.g., start-stop switches); (2) online hand-

rinsing facilities with a continuous flow of water within easy access; and (3) 200 foot-candles of shadow-free lighting with a minimum color-rendering index value of 85. These requirements, together with the immediate corrective actions taken by the establishments and with Korea's history of taking effective action to resolve deficiencies found in an audit, provide a basis for FSIS to have confidence that the deficiencies that the auditors found in the establishments have been corrected and will not recur.

The second problem regarding the implementation of laboratory quality systems within Korea's National Residue Program and Microbiological Testing Program was identified in two equivalence components, Chemical Residue Testing Programs and Microbiological Testing Programs. Specifically, the CCA did not have adequate control over the implementation of quality systems in the government laboratories that are part of Korea's poultry inspection system. While residue and microbiological testing methods appeared to be implemented in an appropriate manner, Korea's CCA was not verifying that the quality control and assurance programs implemented by the government laboratories were adequate. For example, the frequency and the documentation of equipment verification, calibration, and maintenance related to relevant testing methods varied among the

laboratories and were not consistent with international standards. Therefore, Korea did not consistently implement adequate standards for the laboratories.

Following the 2010 audit, Korea submitted documents showing that it had implemented quality control and assurance programs. The documentation provided shows that Korea adopted procedures consistent with U.S. procedures to ensure that laboratory equipment and materials are appropriately verified, calibrated, and maintained to meet program requirements (Accreditation Guide 04/10, quality system recommendation in accordance with ISO/IEC 17025 international standards). Korea submitted documents to show that the Korean CCA has adequately trained laboratory managers and staff in the quality control and assurance program procedures. Records show that Korea has audited the government laboratories involved in poultry inspection at least once per year, and that the laboratories are meeting Korea's quality system requirements. FSIS's review of proficiency testing reports for the year 2012 submitted by Korea in September 2013 found that the participating Korean government laboratories are effectively using the FSIS laboratory testing methods to ensure that products eligible for export to the U.S. are free of contamination. The documents that Korea submitted to FSIS collectively demonstrate that the Korea CCA has effectively

implemented procedures in its quality control and assurance programs that are equivalent to U.S. procedures.

Comment: Finally, the consumer advocacy organization stated that FSIS should not find Korea equivalent when FSIS is not performing annual audits of all countries currently listed as eligible to export to the United States.

Response: FSIS will conduct on-site audits of Korea's inspection system each year for the next three years. After three years, FSIS will reassess how frequently it needs to conduct on-site audits of Korea's system. Additionally, all product imported from Korea will be subject to FSIS re-inspection.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866 by the Office of Management and Budget (OMB) and has been determined to be not significant for purposes of E.O. 12866.

Economic Impact Analysis

This rule adds Korea to the list of countries eligible to export poultry products into the United States. Korea will export two types of ginseng chicken stew products to the United States. Given the limited market in the United States for this product, and the projected export volume of this product from Korea, the impact on the United States economy is likely to be

very small. According to data from Korea, only two Korean establishments will export ginseng chicken stew to the United States. The average combined annual production of these two establishments is 3.2 million pounds (2006-2010 average), and their projected total export volume to the United States will be about 380,000 pounds in year one (the first year of exporting to the United States), gradually increasing to about 2.25 million pounds in year five, according to the Korean data.

Ginseng chicken stew is sold commercially in frozen pouches. The United States market for ginseng chicken stew is so small that no data on domestic production, consumption, or importation could be found. Using label application data, FSIS identified two official establishments that produce and sell ginseng chicken stew. On the basis of information from these establishments, FSIS believes (1) they are very likely the only two establishments that are producing ginseng chicken stew in the United States, (2) the market for ginseng chicken stew is limited, (3) the annual production is about 18,000 pouches for one establishment and 10,000 pouches for the other, and (4) each pouch weighs about two pounds. Therefore, the combined production of these two establishments is about 56,000 pounds per year $((18,000 + 10,000) \times 2)$. The special flavor and taste make ginseng chicken stew unlikely to be a substitute for other

kinds of chicken stew in the United States. Therefore, although this rule may affect these two United States establishments, the impact to the United States economy is likely to be insignificant.

Expected benefits from this rule will be primarily for consumers in the form of more choices in the marketplace. As mentioned above, the volume of trade stimulated by the rule is likely be so small as to have little effect on supply and prices. Another potential benefit of this rule would result in efficiency gains of United States poultry producers due to the increased competition from Korea.

The cost of this rule will be incurred by domestic producers in the form of competition from Korea. The two establishments that are currently producing ginseng chicken stew are likely to encounter competition pressure, for the projected import volume in year one is already 6.8 times the combined production volume of these two establishments. The imported volume, however, is likely to have little impact on the overall United States economy. Also, these two establishments may change their production mix if they find it difficult to compete with imports.

Effect on Small Entities

The FSIS Administrator has made a determination that this rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). As mentioned above, the expected trade volume will be very small, and the effect will be on only two very small establishments that produce ginseng chicken stew domestically.

Potential Long-term Effect

When foreign countries apply for eligibility of their meat, poultry, or egg products for entry into this country, FSIS determines whether their inspection systems are equivalent to the system maintained by the United States. FSIS does not make equivalence determinations on the basis of particular products; rather, the equivalence decision is based on the evaluation of the countries' inspection systems.

Although Korea indicates that it intends to export two types of ginseng chicken stew products for now, it would not be precluded from exporting other poultry products in the future if the products meet all applicable APHIS and FSIS requirements for those products. If additional Korean establishments export product to the United States, the long-term economic impact could be more significant. However, no data is available to assess such future impacts.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

No new paperwork requirements are associated with this final rule. Foreign countries wanting to export poultry and poultry products to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. FSIS provided Korea with questionnaires asking for detailed information about the country's inspection practices and procedures to assist that country in organizing its materials. This information collection was approved under OMB number 0583-0094.

E-Government Act

FSIS and the United States Department of Agriculture (USDA) are committed to achieving the purposes of the E-Government Act

(44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this rule and will announce it on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules>.

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The Update also is available on the FSIS Web page. In addition, FSIS offers an e-mail subscription service which

provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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List of Subjects in 9 CFR Part 381

Imported products.

For the reasons set out in the preamble, FSIS is amending 9 CFR part 381 as follows:

Part 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C 451-470; 7 CFR 2.7, 2.18, 2.53.

§ 381.196 [Amended]

2. Amend § 381.196(b) to add the "Republic of Korea" in alphabetical order to the list of countries.

Done at Washington, DC on: March 20, 2014.

Alfred V. Almanza,

Administrator.

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